

## REMARKS

### Summary of the Invention

The invention relates to a method of identifying patients to receive cholinomimetic drugs as treatment for neurological disease. Patients that are to receive cholinomimetic therapy are identified by determining the number of copies of apoE4 gene alleles.

### Summary of the Office Action

Claims 1-8 are pending and stand rejected. Claim 6 is rejected under 35 U.S.C. § 112, first paragraph. Claims 1-8 are rejected under 35 U.S.C. § 112, second paragraph. Claims 1-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Poirier WO 95/29257. Claims 1-8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Poier et al., Proc. Natl. Acad. Sci. USA (1995) 92:12260-12264 and Roses et al. US 5,508,167. Each of these issues is addressed below.

### Priority Claim

Applicant amended the specification to reference the application to which priority is claimed. Additionally, to reflect this priority claim Applicant has submitted herewith a petition to correct the filing receipt.

### Support for the Amendment

Claim 8 has been amended to remove canceled claim 6. No new matter is added by this amendment.

#### Rejection under 35 U.S.C. § 112, First Paragraph

Claim 6 is rejected under 35 U.S.C. § 112, first paragraph, as not enabling one skilled in the art to practice the invention commensurate in scope with these claims.

Applicant has cancelled this claim. Consequently, the rejection under 35 U.S.C. § 112, first paragraph, is now moot and may be withdrawn.

#### Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-3 and 8 are rejected for failing to particularly point out and distinctly claim the subject matter, which the Applicant regards as the invention. Specifically, the Examiner based the rejection on the assumption that the claims do not set forth the steps that would be taken to determine the number of apoE4 alleles in a subject. Applicant respectfully submits that one skill in the art would know to steps to determine the number of apoE4 alleles in a subject (Watson, *et al.*, Recombinant DNA 2<sup>nd</sup> Ed., New York : Scientific American Books, 1992). None the less, Applicant directs the Examiner's attention to the description of a polymerase chain reaction that can be used to determine the number of apoE4 alleles (pages 7, lines 23- 35 and page 8, lines 1-15, and Figure 1). Accordingly, additional instruction as to determine the number of apoE4 alleles is not required for enablement of the present invention.

Rejections under 35 U.S.C. § 102 (b)

Claims 1-8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Poirier WO 95/29257. The Poirier WO 95/29257 is the PCT publication of United States patent application 08/727,637 upon which the Applicant claims priority. Consequently, the rejection under 35 U.S.C. § 102 (b) is now moot and may be withdrawn.

Rejections under 35 U.S.C. § 103 (a)

Claims 1-8 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Poirier et al. Proc. Natl. Acad. Sci. USA (1995) 92:12260-12264 and Roses et al. US 5,508,167 (April 16, 1996). Because these references were published more than one year after the application from which the present application claims priority, Applicant submits that these references are not appropriate to serve as the basis of a 35 U.S.C. § 103 (a) rejection. Consequently, the rejection under 35 U.S.C. § 103 (a) is now moot and may be withdrawn.

Conclusion

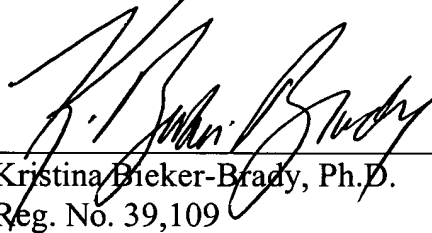
Applicant submits that the claims are in condition for allowance and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for 3 months, to and including October 13, 2001. If there are any charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date:

*October 15, 2001*

  
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APOLIPOPROTEIN E POLYMORPHISM AND TREATMENT  
OF ALZHEIMER'S DISEASE  
Our Ref.: 50211/005002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

6. Cancel
7. Cancel
8. (Amended) The method of claims 1, 2, 3, 4, or 5[, or 6]wherein said drug is  
tacrine.